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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,992	06/09/2005	Hiroshi Matsui	081356-0243	1370

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EXAMINER	
MARTIN, PAUL C	
ART UNIT	**PAPER NUMBER**
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,992	MATSUI, HIROSHI	
	Examiner	Art Unit	
	Paul C. Martin	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 13-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 13-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 13-29 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/26/07 has been entered.

Response to Arguments

Applicant's arguments, see Remarks, filed 03/26/07, with respect to the rejection(s) of claim(s) 1-12 under 35 U.S.C. § 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Nakamura *et al.* (US 6,333,166 B1). Further the offer of allowable subject matter in the interview and draft of 05/29/2007 is withdrawn.

Double Patenting

Claims 1, 13-15, 20, 21, 25, 26 and 28 of this application conflict with claims 1-5, and 7-13 of Application No. 10/594898. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13, 20, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura *et al.* (US 6,333,166 B1).

Nakamura *et al.* teaches a method comprising: introducing into a serum sample (inherently containing serum albumin) a first reagent in an automated analyzer; comprising a surfactant that acts only on lipoproteins other than LDL (Emulgen B66), cholesterol esterase and cholesterol oxidase to generate hydrogen peroxide and measuring the generated hydrogen peroxide through the reaction with 4-aminoantipyrine (4-AAP), then introducing a second reagent that acts on the LDL to generate additional hydrogen peroxide and measuring the elevated absorbance, wherein the second value represents the total cholesterol in the serum sample and the difference in the first absorbance and second absorbance represents the amount of LDL (Column 5, Lines 31-54).

Claims 25, 27, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsui *et al.* (US 6,194,164 B1).

Matsui *et al.* teaches a kit comprising a first and second reagent, wherein the first reagent comprises a surfactant that acts only on lipoproteins other than LDL (Emulgen B66), *Pseudomonas* cholesterol esterase, cholesterol oxidase and the hydrogen donor compound HDAOS and wherein the second reagent comprises a surfactant that acts on a least LDL (Triton X-100) peroxidase, and 4-aminoantipyrine (Column 6, Lines 20-38). The composition of Claims 25-29 is more properly examined as a kit as the components do not become a composition until actual mixture takes place.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsui *et al.* (US 6,194,164 B1).

The teachings of Matsui were discussed above.

Matsui *et al.* does not teach wherein the first reagent comprises peroxidase, 4-AAP and a hydrogen donor compound.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the kit of Matsui *et al.* to include 4-AAP in with the first reagent because one of skill in the art would have recognized that the reaction components were interchangeable.

One of ordinary skill in the art would have been motivated to make this change because the comprising language of the claim leaves the exact reagent components open to additional ingredients such that one of skill in the art could rearrange reaction components in the kit depending upon artisan preference. There would have been a reasonable expectation of success in making this modification because Matsui *et al.* teaches a kit containing all of the claimed reagent components.

Claims 1, 13-16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (US 6,333,166 B1) in view of Matsui *et al.* (US 6,194,164 B1).

The teachings of Nakamura *et al.* and Matsui *et al.* were discussed above.

Nakamura *et al.* does not teach the use of colored quinone hydrogen donating compound or wherein the cholesterol esterase is from *Pseudomonas.*

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the method of determining total and LDL cholesterol as taught by Nakamura *et al.* with the method of determining LDL cholesterol as taught by Matsui *et al.* because both methods utilize similar reactions and components to determine LDL cholesterol.

One of ordinary skill in the art would have recognized that the colored quinone and bacterial cholesterol esterase were functional equivalents of the cholesterol esterase and 4-AAP used in the method of Nakamura *et al.* and the use of both in cholesterol determination was certainly well known at the time of the instant invention. There would have been a reasonable expectation of success in making this combination because of the similarity in the two methods, both using similar compounds and reactions to determine LDL cholesterol.

Claims 1, 13, 17, 18, 20, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (US 6,333,166 B1) in view of Sugiuchi (US 6,794,157 B1).

The teachings of Nakamura *et al.* were discussed above.

Nakamura *et al.* does not teach the use of cholesterol dehydrogenase or NAD.

Sugiuchi teaches a method of quantitating LDL cholesterol with a reagent composition containing cholesterol dehydrogenase, cholesterol esterase and oxidized coenzyme (NAD) wherein reduced coenzyme is measured (Column 20, Claim 1 and Column 10, Lines 11-12).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of determining total and LDL cholesterol as taught by Nakamura *et al.* with the method of determining LDL cholesterol of Sugiuchi because both techniques utilize similar methods to enzymatically determine LDL cholesterol. One of ordinary skill in the art would have recognized that the two references teach alternate means of arriving at the same conclusion, the amount of LDL cholesterol and the choice of enzymatic pathway would have been dependent upon artisan preference. There would have been a reasonable expectation of success in making this combination because Sugiuchi teaches cholesterol determination by both pathways and enzyme combinations.

Claims 1, 13, 20, 21, 22, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (US 6,333,166 B1) in view of Kishi *et al.* (US 2003/0129681 A1).

The teachings of Nakamura *et al.* were discussed above.

Nakamura *et al.* does not teach wherein the first step of the reaction is carried out in the presence of lipoprotein lipase and albumin.

Kishi *et al.* teaches a method of determining VLDL comprising the use of albumin and lipoprotein lipase and wherein albumin is added to suppress the reactivity of LPL with HDL (Pg. 2, Paragraph [0015]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of determining total and LDL cholesterol as taught by Nakamura *et al.* with the method of determining VLDL cholesterol of Kishi *et al.* because both methods are drawn to similar methods of enzymatic determination of specific lipoproteins. One of ordinary skill in the art would have recognized that lipoprotein lipase is a functional equivalent of the cholesterol esterase of Nakamura *et al.* both of which hydrolyze lipoprotein to release the components therein. One of ordinary skill in the art would have been aware and motivated, based upon the teachings of Kishi *et al.* to provide albumin when using LPL in order to prevent cross-reactivity with other lipoproteins. There would have been a reasonable expectation of success in making this modification because both methods are drawn to the use of similar methods and reagents in the quantitative determination of lipoproteins.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

6/7/07

Jon Weber
Supervisory Patent Examiner